AQUALUNG
THERAPEUTICS
TARGETING RUNAWAY INFLAMMATION

AQUALUNG THERAPEUTICS RECEIVES FDA CLEARANCE TO PROCEED WITH THE P2A PUERTA STUDY IN SUBJECTS WITH MODERATE/SEVERE ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

- Aqualung Therapeutics will initiate moderate/severe ARDS patient recruitment for U.S. and Australia hospital sites in August 2023.

-Aqualung appoints Jackson Streeter MD to their board of directors bringing expertise to Aqualung to support advancing of ALT-100 mAb as a novel therapeutic for inflammatory and fibrotic diseases (ARDS, radiation-induced lung fibrosis, pulmonary arterial hypertension)

TUCSON, AZ/JUPITER, FL/ Accesswire/18 July, 20232/ Aqualung Therapeutics, an early stage immunotherapeutics company with an anti-inflammatory and anti-fibrotic therapeutic platform for life-threatening unchecked inflammation/fibrosis, is pleased to announce FDA clearance to proceed with their P2A study in moderate/severe ARDS patients. Additionally, Aqualung is pleased to announce the addition of Jackson Streeter MD as a member of the company board of directors.

Following an End of Phase 1 (EOP1) May 2023 meeting with the U.S. FDA to review the Phase 1A safety data with ALT-100 mAb in healthy human volunteers, Aqualung has now received FDA clearance to proceed with the P2A PUERTA clinical trial designed to test the ALT-100 mAb in moderate/severe ARDS patients. This major milestone highlights the FDA's positive review of key safety data results in the P1A study. More importantly, this demonstrates acceptance by the FDA on the study design of the P2A study in moderate/severe ARDS patients which has comprehensive inclusion and exclusion criteria. "Our team has worked diligently to submit all of the required regulatory documents and we are glad the FDA agrees with our study design and our mission to demonstrate the potent anti-inflammatory and anti-fibrotic benefits in hospitalized patients diagnosed with moderate/severe ARDS" states Stan Miele President & CBO of Aqualung Therapeutics. "With still no

FDA-approved ARDS therapies, there is a significant clinical need for novel therapies to address the 30-40% ARDS mortality rate." Aqualung has also submitted the necessary regulatory documents to the Australian health authorities (HREC) and anticipates approval within a matter of weeks. Patient enrollment at sites in the U.S. (minimum of eight sites) and Australia (two sites) may begin as early as August 2023.

Dr. Streeter is the Life Science expert amongst the DeepWork Capital partners and has a dual role as the Director of Ventures at the University of Florida. Previously, he founded the medical technology companies PhotoThera and American Veterinary Laser, and he was the CEO of Banyan Biomarkers. He also served as Senior Vice President of Corporate Development and Strategy at Quanterix (NASDAQ: QTRX) and as the CEO of the Institute for the Commercialization of Public Research, which has the mission of funding early-stage companies throughout the state of Florida. Dr. Streeter has had several successful exits with companies he founded or as a C-level executive.

Dr. Streeter's board appointments have included Florida Research Consortium, Governor's Life Science Task Force for the State of Florida, FBI Counter Terrorism Southeast Working Group, Walter H. Coulter Center Committee at the University of Miami and the Gainesville Chamber of Commerce Board of Directors. Dr. Streeter also served as an Officer in the U.S. Navy. He earned his B.S. degree in Biology from the University of Nevada Reno and his M.D. from the University of Nevada School of Medicine. He's the inventor of 20+ patents and author on multiple scientific publications.

"Aqualung is honored to have Dr. Streeter as a new member of our board" states Joe GN Garcia MD, CEO and Founder of Aqualung Therapeutics. "Jackson brings a wealth of knowledge and experience in biotech, bringing products through clinical development, and he will provide great insight as Aqualung transitions into a full-fledged clinical development company. We welcome institutional investors whose teams will provide great value to the growth of the company, and Deepwork Capital and the Florida Opportunity Fund have a history of being highly engaged with companies that are part of their portfolio."

With a recent $1.5M investment from Florida Opportunity Fund and Deepwork Capital, Aqualung is poised close the series A capital raise in the coming months, allowing the company to complete the P2A PUERTA ARDS trial and to submit INDs for the chronic indications of Radiation Lung Fibrosis and Pulmonary Arterial Hypertension to the FDA by mid-2024.

The ALT-100 mAb targets extracellular NAMPT or eNAMPT, a master regulator of systemic inflammation and fibrosis that was identified by Dr. Garcia as a novel therapeutic target and major contributor to the severity of ARDS and other severe disorders characterized by inflammation and organ fibrosis.

About Aqualung Therapeutics Corporation

Aqualung is an early-stage biotech immunotherapeutics company which has developed an anti-inflammatory therapeutic platform for patients with life-threatening unchecked inflammation. Founded in 2016 and led by a physician-scientist, Aqualung's science-driven approaches led to the identification of nicotinamide phosphoribosyltransferase (NAMPT) as a major contributor to the severity of potentially fatal inflammatory diseases. Aqualung Therapeutics has developed eNamptor™, a Next Gen platform comprised of: i) the humanized ALT 100 mAb, an eNAMPT-neutralizing monoclonal antibody; ii) eNAMPT-Plex, a plasma-based biomarker panel comprised of cytokines and eNAMPT, which predicts ARDS mortality; and iii) *NAMPT*-Gene, a genotyping assay that identifies individuals genetic variants that predispose to ARDS risk and death. In addition to ARDS and ventilator-induced lung injury, the pipeline of ALT-100 mAb indications currently includes intrauterine infections during pregnancy (chorioamnionitis), prostate cancer, pulmonary hypertension, autoimmune disorders (IBD, SLE) and fibrosis of cardiac (post ischemic), pulmonary (IPF, radiation) and hepatic tissues (NASH). Each of these potentially fatal inflammatory conditions exhibits significant unmet medical needs for therapeutics to reduce morbidity and mortality. For additional information about the company, please visit *www.aqualungtherapeutics.com.*

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